REMARKS

In the outstanding Office Action, claims 19-45 and 64 were presented for examination. The claims were rejected for obviousness in view of Bretz, Brandau, Grulke and Tremont. Respectfully, Applicant notes that these references, neither alone nor in combination, teach or even suggest the claimed invention, which involves preparing polymer gel particles having dispersed therein a restraining polymer ionically bonded to at least one active agent.

Claims 32-35 were rejected under 35 USC 112 as failing to comply with the written description requirement noting that while the specification discloses agar and polysaccharides, claim 32 recites synthetically modified polysaccharides and proteins, synthetic and natural polymers, and botanically derived gels. As filed, claim 4 recites modified polysaccharides. In addition, and perhaps more importantly, the specification at paragraph 59 specifically recites:

> "Other such possible gels will be known or apparent to those skilled in the art, in the light of the disclosure herein, and may include: synthetic polymers, such as vinyl or acrylamide polymers, or copolymers; natural polymers, for example polysaccharides, or proteins or synthetically modified ones of such polymers; botanically derived gels; and may include gelling agents such as carbopol, a common, low-cost petroleum-derived, cosmetic gel."

Accordingly, it is believed that the claim 32 thus complies with the written description requirement. Claims 33-35 have been canceled.

Claims 19-45 and 64 were rejected under 35 USC 112 as failing to comply with the enablement requirement, in that while the specification teaches the use of agar, synthetic polymers, vinyl polymers and copolymers, natural polymers, proteins and

gels are not reasonably enabled. Applicant respectfully disagrees. There is cited invention is a mechanical gel delivery system which involves heating and cooling of the gel and the formation of droplets. It does not depend upon the chemical properties of the gel to form specialized chemical bonds or undergo other chemical processes. Accordingly, the claims are clearly enabled.

Claims 19-45 and 64 were rejected under 30 privacy 112 as being indefinite for inclusion of the terms "hot" and "cold". These terms have been removed from the claims.

Turning to the prior art rejections, the patent to Bretz completely fails to anticipate the disclosure of the present invention. He does not teach the use of a restraining polymer which is central to the claims of the present application. In addition, he does not teach the use of ionic bonding of a restraining polymer to an active agent. Instead, he teaches the mere incorporation of additives into or coated onto porous polymer beads, something not remotely related to the technology of the present invention.

While, to be fair, reference has been made to Tremont in an attempt to buttress the failings of Bretz, this patent fails to address principal issues created by Bretz. Specifically, Tremont teaches a delivery system which completely fails to anticipate or render obvious the inventive two polymer delivery system. Accordingly, the claims are believed to be clearly allowable. They are not only limited to a two polymer system, but also to a system in which one of the polymers is a gel and wherein the molecular weight of the other polymer results in its being restrained within the gel. The Tremont disclosure involving the use of a linker molecule that is not a polymer, in which the linker molecule has reactive substituents that covalently bond to an active ingredient as well as to a cross-linked polymer is completely remote to the invention in numerous aspects.

Accordingly, Tremont does not teach or even suggest a two polymer delivery system comprised of a restraining polymer dispersed in polymer gel particles, as claimed in claim 19, in which the restraining polymer is ionically bonded to an active agent, as claimed in claims 66 and 69.

In addition, Tremont is silent with respect to a restraining polymer dispersed in polymer gel particles in which the restraining polymer has sufficient molecular weight to prevent egress of the restraining polymer from the gel particles, as claimed in claims 19 and 69. That is because Tremont solely teaches non-polymeric linker molecules that are covalently bonded to cross-linked polymers and, as such, such egress would not occur due to the covalent bonds.

Grulke and Brandau do not cure the deficiencies of Tremont or Bretz. As alluded to above, Tremont fails to disclose a restraining polymer ionically bonded to at least one active agent, in which the restraining polymer is dispersed in polymer gel particles.

Bretz, as alluded to above, fails to disclose the use of a water-based solution of a polymeric gelling agent, nor does he disclose the use of a restraining polymer dispersed in polymer gel particles, in which the restraining polymer is bonded to at least one active agent and has a sufficient size to prevent egress of the restraining polymer bonded to the at least one active agent from the gel particles, as claimed in claim 19. In addition, he fails to disclose the use of ionic bonding of a restraining polymer to an active agent, as claimed in claims 66 and 69.

Grulke fails to disclose the use of a polymeric gelling agent, as well as the use of a restraining polymer bonded to at least one active agent, in which the restraining

polymer is dispersed in polymer gel particles, and in which the restraining polymer is bonded to at least one active agent and has a sufficient size to prevent egress of the restraining polymer bonded to the at least one active agent from the gel particles, as claimed in claim 19. He also fails to disclose that the restraining polymer is ionically bonded to the at least one active agent, as claimed in claims 66 and 69.

Brandau fails to disclose the use of a water-based solution of a polymeric gelling agent, nor does he disclose the use of a restraining polymer dispersed in polymer gel particles, in which the restraining polymer is bonded to at least one active agent and has a sufficient size to prevent egress of the restraining polymer bonded to the at least one active agent from the gel particles, as claimed in claim 19. In addition, he fails to disclose the use of ionic bonding of a restraining polymer to an active agent, as claimed in claims 66 and 69.

Finally, none of the references cited by the Examiner are in the analogous field of the claimed invention, which is directed to a gel delivery system comprised of polymer gel particles having dispersed therein a restraining polymer ionically bonded to at least one active agent for topical application of the active agent to a subject. Rather, Bretz is directed to producing porous, spherical polymeric particles in the non-nanoscalar range; Brandau is directed to producing narrow, grain-sized non-polymeric spherical particles out of a liquid phase from substances having a high melting point; Tremont is directed to producing a delivery system for drugs comprised of an active ingredient covalently bonded to a non-polymeric linker molecule, which in turn is covalently bonded to a portion of a cross-linked polymer; and Grulke merely provides a handbook directed to polymers.

In view of the fact that Bretz, Brandau, Grulke and Tremont fail to disclose or even remotely suggest, either alone or in combination, a method of preparing a gel

delivery system comprising polymer gel particles for topical application of at least one active agent, in which the polymer gel particles have dispersed therein a restraining polymer bonded to at least one active agent, it is respectfully submitted that claims 19-45, 64 and 70 are clearly drawn to patentable subject matter, and such action is respectfully sought.

In addition, in view of the fact that Bretz, Brandau, Grulke and Tremont fail to disclose or even remotely suggest, either alone or in combination, a method of preparing a gel delivery system comprising polymer gel particles for topical application of at least one active agent, in which the polymer gel particles have dispersed therein a restraining polymer ionically bonded to at least one active agent, it is respectfully submitted that claims 66-69 are clearly drawn to patentable subject matter, and such action is respectfully sought.

It is submitted that the claimed language does not justify the rejection of the claims as being obvious over Bretz, Brandau, Grulke and Tremont, and thus this rejection should be withdrawn.

The Commissioner is authorized to charge any additional fees required or to credit any overpayment to Deposit Account No. 20-0809.

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Respectfully submitted,

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